National Patient Safety Partnership

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May 12, 1999

FOR IMMEDIATE RELEASE

HEALTHCARE LEADERS URGE ADOPTION OF METHODS TO REDUCE ADVERSE DRUG EVENTS

Washington, D.C. – A coalition of healthcare organizations today released recommendations for reducing the occurrence of adverse drug events.

Stressing that this is a problem that neither government nor individual healthcare organizations can solve working alone, Kenneth W. Kizer, M.D., M.P.H., U.S. Department of Veterans Affairs' (VA) Under Secretary for Health, said the public-private National Patient Safety Partnership[1] is urging consumers, healthcare practitioners, healthcare provider organizations and healthcare purchasing cooperatives to adopt successful methods of preventing adverse drug events.

"Treatment-related adverse drug events are a major problem in this country that exact high costs in patient morbidity and mortality as well as dollars," said Dr. Kizer. "The Partnership can make significant patient safety improvements through advocacy of best practices to reduce errors associated with prescribing, purchasing, dispensing and administering of medications."

The patient safety group encouraged healthcare practitioners and healthcare provider organizations to commit to certain best, or model, practices and work together to implement them, in partnership with consumers, patient advocacy groups, and the pharmaceutical industry. Their recommendations follow.

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[1]The NPSP is a voluntary public-private partnership dedicated to reducing preventable adverse medical events. Its charter members include American Hospital Association*, American Medical Association*, American Nurses Association*, Association of American Medical Colleges*, Agency for Health Care Policy and Research, Food and Drug Administration, Health Care Financing Administration, Joint Commission on Accreditation of Healthcare Organizations*, Institute for Healthcare Improvement*, National Institute for Occupational Safety and Health, National Patient Safety Foundation at the AMA*. Department of Defense – Health Affairs, and Department of Veterans Affairs*. *Charter Organizations

To reduce the occurrence of adverse drug events (events that can cause, or lead to, inappropriate medication use and patient harm),

Patients can:

- Tell physicians about all medications they are taking and responses/reactions to them
- Ask for information in terms they understand before accepting medications

Providing Organizations and Practitioners can:

- Educate patients
- Put allergies and medications on patient records
- Stress dose adjustment in children and older persons
- Limit access to high hazard drugs
- Use protocols for high hazard drugs
- Computerize drug order entry
- Use pharmacy-based IV and drug mixing programs
- Avoid abbreviations
- Standardize drug packaging, labeling, storage
- Use “unit dose” drug systems (packaged and labeled in standard patient doses)

Purchasers can:

- Require machine-readable labeling (barcoding)
- Buy drugs with prominent display of name, strength, warnings
- Buy “unit of use” packaging (aka “unit dose”)
- Buy IV solutions with two sided labeling

-more-

To reduce the potential for taking a medication that was not prescribed for them or cannot be safely taken by them, patients should ask the following five sets of questions before accepting prescription drugs.

- Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?
- What is the drug for? What is it supposed to do?
- How and when am I supposed to take it and for how long?
- What are the likely side effects? What do I do if they occur?
- Is this medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

# # #

National Patient Safety Partnership

Statement Regarding
Its Initiative to
Reduce Preventable Adverse Drug Events

Various studies have shown that adverse drug experiences or events affect between 2 and 35 percent of hospitalized patients. Preventable adverse drug events represent a significant subset of these, if not a large majority of them. Little is known about the incidence of adverse drug events in outpatients, although they have been shown to be a significant cause of hospitalization and, consequently, increased health care costs. Indeed, adverse drug events are a cause of increased healthcare costs in all care settings.

For this initiative, a preventable adverse drug event (PDE)[1] is defined as an event that can be anticipated and forestalled and that will cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding or dispensing; distribution; administration; education; monitoring; and use.[2] Overall, PDEs are a serious public health and medical care problem because of the large number of drugs, doses, and drug treatment regimens currently available and the many changes in the manner that healthcare is provided today.

The National Patient Safety Partnership is a public-private partnership dedicated to improving healthcare in general and patient safety in particular by reducing adverse events and untoward outcomes of healthcare or healthcare-related processes. The members of the Partnership believe there are significant patient safety improvements that can be made through the prevention of avoidable adverse events associated with the prescribing, dispensing and administering of medications.

The members of the National Patient Safety Partnership believe that prevention of medication-related adverse events will be maximized when the outcomes of specific actions for improvement can be reliably predicted based on a strong body of evidence. It realizes that the current evidence base needs strengthening and believes that iterative improvement accompanied by outcomes analysis can advance the state of the science toward that goal. Based on current knowledge, the Partnership has identified a number of “best practices” or “model practices” that could substantially reduce the potential for occurrence of PDEs, and the Partnership calls on healthcare consumers, patient advocacy groups, the pharmaceutical industry, healthcare practitioners and healthcare organizations to make a commitment to adopt the practices listed below and to work together to implement them, as well as to develop additional ways to reduce PDEs.

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[1] The differences between a PDE and the Food and Drug Administration’s (FDA) broader statutory definition of an adverse drug experience or event should be recognized. The National Patient Safety Partnership’s principal interest is advancing practices that prevent adverse events whereas the FDA’s principal interest is understanding drug/drug interactions and the biologic activity of drugs so they are fully labeled. At 21 CFR section 314.80 FDA defines an adverse drug experience as any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

[2] Adapted from the USP Quality Review – Definition of Medication Errors

Model Practices to Prevent Adverse Drug Events[3]

Current Best Practices For Patients/Consumers

The members of the National Patient Safety Partnership believe that all patients should be actively involved in their care and decisions concerning their care. There are many actions that patients can take, but the following two are stressed as ways to ensure that medication-related information is exchanged in a way that increases the probability of safe care.

1. Patients (or their personal advocates) should always inform their physician or other healthcare practitioner of all medications they are taking (NB: This includes prescription medication, over-the-counter medication and dietary supplements.) as well as about any and all allergies or previous adverse drug experiences they have experienced before accepting any new medication. Patients should not assume that information previously provided has been communicated or has been considered prior to a medication being prescribed or administered.

2. Patients (or their personal advocates) should request information about medications in terms that they can understand, both at the time the medication(s) is/are being prescribed and when they are received. This applies to prescription and over-the-counter medications. Patients should ask for information about the intended use or purpose of the drug, possible drug-drug interactions, potential hazards associated with taking several medicines (e.g., more than 3 drugs at the same time), and about changes in the appearance of any medications they have been taking (such as when a prescription refill is a different color from what had previously been taken). Before accepting or receiving a prescription, the patient should always ask the following questions:

    - Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?
    - What is the drug for? What is it supposed to do?
    - How and when am I supposed to take it and for how long?
    - What are the likely side effects? What do I do if they occur?
    - Is this new medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

In addition, at the time prescription medications are received from pharmacies, patients should ask if the drug they are receiving is the one their doctor or other health care provider ordered and ask that both the trade and generic names be listed on the prescription label.

[3] The ordering of these "Best Practices" is not intended to suggest relative importance. The "Best Practices" are identified on the basis of eight techniques or criteria that have been shown to be important in reducing errors in general and medication errors in particular. The eight criteria are 1) ensuring timely access to information; 2) standardization; 3) simplification; 4) reduced reliance on memory; 5) reduced reliance on practitioner vigilance; 6) broad application; 7) cost effectiveness of the intervention; and 8) established success of the intervention. The 16 practices are used in the Institute for Healthcare Improvement Breakthrough Series.

Current Best Practices For Providing Organizations and Practitioners

The members of the National Patient Safety Partnership believe that healthcare organizations and practitioners are committed to safeguarding patients and call upon both organizations and individual practitioners to further advance the following practices and to support and advocate for these actions in areas and organizations in which they are not utilized.

3. Educate patients, family members and other caregivers about all medications (both prescription and over-the-counter, including dietary supplements) that are used. (Emphasis should be placed on the hazards of polypharmacy, drug-drug interactions and possible adverse effects.) Patients and caregivers should be encouraged to ask for information about all medications and dietary supplements, especially when new medications are prescribed or changes in medications are made.

4. Prominently display critical patient information, such as drug allergies and medication regimens, on every patient record.

5. Emphasize the need for dose adjustment in children and elderly patients. In some elderly patients, a reduction in dose may be required because of age-related changes in body mass and organ function.

6. Limit accessibility to and control the use of highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.

7. Insist on the development and use of protocols for highly toxic or hazardous drugs with a narrow therapeutic range. (Computerized drug order entry systems can be especially important in facilitating this with alerts, restrictions or suggestions for safer substitutes.)

8. Computerize drug order entry whenever possible. If computerized drug order entry is not feasible, then use pre-printed order forms for drugs in inpatient settings and, where appropriate, in ambulatory care settings.

9. Utilize pharmacy-based intravenous (IV) admixture programs.

10. Avoid the use of abbreviations whenever possible; if abbreviations are used, they should be standardized throughout the organization and their use minimized.

11. Standardize approaches and processes for drug storage locations, internal packaging or labeling and delivery, and require use of the standardized approaches and processes.

12. Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate.

Current Best Practices For Purchasers

The members of the National Patient Safety Partnership believe that while most of these practices advocated in this initiative would cost little or nothing to implement, they do recognize that an investment will be required for some and call upon healthcare organizations and the pharmaceutical industry to make any needed investment in the interest of patient safety.

13. Require machine-readable labeling, such as a barcoding system, complete with pertinent information such as lot number and expiration date.

14. Preferentially purchase products that have labels with name of drug, concentration and warnings prominently displayed and that otherwise incorporate human factors evaluation into naming, labeling and packaging processes. (For example, the use of large type or contrasting colors to avoid look-alike packaging or unheeded warnings.)

15. Preferentially purchase and utilize "unit of use" packaging in inpatient settings; also use such packaging in outpatient (ambulatory care) settings, where appropriate.

16. Preferentially purchase intravenous (IV) solutions with contents and concentration prominently displayed on both sides of the container.

Even Better Practices in the Future

Finally, the members of the National Patient Safety Partnership believe it is imperative that the healthcare and pharmaceutical industries launch and sustain collaborations directed toward systematic approaches to the prevention of PDEs. The Partnership challenges these industries to seek opportunities for research and to seek collaborations to identify better practices in the future, to prioritize practice interventions, and to define practices that can predictably effect improvement in terms of increased safety and cost-effectiveness. Integral to such an activity is a non-punitive culture that encourages reporting of adverse or unexpected events to relevant oversight bodies, including internal quality management systems and regulatory agencies, and that provides feedback about resulting lessons learned and system changes aimed at preventing future such events. To be truly successful these activities must be ongoing since no solution that is found to any problem can be thought of as the "solution for all time". A spirit of continual and relentless examination and reexamination will be necessary to insure that our processes and techniques are appropriate today and that they continue to evolve as necessary to be appropriate in the future as well.

Opening Statement
Of
Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
U.S. Department of Veterans Affairs

May 12, 1999

PREVENTABLE ADVERSE DRUG EVENTS
NATIONAL PATIENT SAFETY PARTNERSHIP

We are here today to talk about a serious public health problem – a problem that has been recognized and talked about for many years, a problem that some experts believe is getting worse, and a problem for which there are readily available and cost effective solutions.

Ironically, this problem of preventable adverse drug events stems from one of the great healthcare success stories of the 20th century, the development of generally safe pharmaceutical products that effectively treat so many different illnesses and health conditions.

As representatives of our individual organizations and as members of the National Patient Safety Partnership we are here today to say it is time to act; it is time to begin to definitively address this problem. In doing this we call upon pharmaceutical manufacturers, healthcare provider organizations, physicians and other caregivers, as well as patients and their families, to each exercise their influence to reduce preventable adverse drug events. In making this call to action we also provide a prescription that if followed could cure three-fourths, if not more, of the problem.

How big of a problem is preventable adverse drug events?

Adverse drug events injure or disable many tens of thousands of Americans every year and add billions of dollars to health care costs. One of the problems is that while we know this is a serious problem, the exact extent of the problem is not known even though many studies of adverse drug events have been published in the medical literature over the past thirty years. These studies show that, on average, about 7% of hospitalized patients will have an adverse drug event. One recent study indicated that as many as 2 million patients may experience an adverse drug event each year. Recent studies have also shown that each one of these events, on average, adds several days of hospitalization to the hospital admission and several thousand dollars to the cost of the hospital stay. We know much less about the frequency or cost of these events in ambulatory or outpatient care, nursing homes, and other sites of care.

In addition, we know that the majority of these adverse drug events are preventable. Indeed, the good news is that these events are preventable with relatively simple interventions. If these simple and straightforward solutions, such as we prescribe here to day, were implemented many thousands of injuries, disabilities and deaths could be prevented and hundreds of millions to billions of dollars of healthcare costs could be saved.

AMERICAN HOSPITAL ASSOCIATION STATEMENT
NATIONAL PATIENT SAFETY PARTNERSHIP PRESS CONFERENCE
ATTRIBUTE TO: JACK LORD, M.D., CHIEF OPERATING OFFICER, AHA
MAY 12, 1999

One of the most important priorities for hospital leaders is to eradicate medical errors in their institutions, and specifically, to reduce errors that occur when medicine is mishandled or misused – thereby endangering patients. The National Patient Safety Partnership recommendations to reduce medication errors will help health care providers make significant improvements.

Most hospitals have systems in place – checks and balances to ensure that errors won't occur. But unfortunately, medication errors can and do occur because of a lack of clear written and oral communication. Transferring information from manufacturer to hospital supply manager to nurse to doctor to patient involves a lot of communication that must be 100 percent accurate.

To identify the cause of errors and increase patient safety, we must increase our own level of awareness of errors that occur within our facilities. Hospitals – and all health care providers – need systems that will catch possible mistakes before they happen. And we believe that one of the most important steps toward improvement is to do what patients tell us they want – to become full partners in decisions about their care and treatment. Improved communication between care givers and patients should contribute to a decline in medication errors.

The AHA is a key player on many national initiatives aimed at reducing preventable medical errors: the National Coordinating Council for Medication Error, Reporting and Prevention; the Institute for Healthcare Improvement; the Institute for Safe Medication Practices; the AMA's National Patient Safety Foundation; and U.S. Pharmacopeia – a not-for-profit foundation to help pharmacists and physicians learn about medication error and prevention.

It will take the involvement of everyone – consumers, physicians, hospitals and other providers of care to prevent medication errors and improve the quality of care.

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U.S. Department of Health and Human Services
Food and Drug Administration
Rockville, MD
May 12, 1999

Earlier this week FDA released a report on managing the risks from medical products. The report acknowledges that all medical products have inherent risks, and that saying a product is "safe" does not mean that it is without risk.

The report emphasizes the advantages of a systems approach to managing that risk. Every group involved in health care – regulators, physicians, patients, others – has its own role. When those roles are clearly defined and acted on, the benefits of medical products will be maximized and their risks minimized.

That's why one of the major recommendations of FDA's report calls for broad policy discussions with stakeholders. And that's why FDA is working closely with the National Patient Safety Partnership in its efforts.

The National Patient Safety Foundation at the AMA

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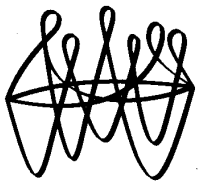

The National Patient Safety Foundation at the AMA (NPSF) recognizes that preventable adverse drug events are an important public health problem which present a challenge for all those involved with pharmaceuticals to communicate, cooperate, and collaborate to ensure their safe and appropriate use. The NPSF's commitment to meeting this challenge is reflected in its participation in the National Patient Safety Partnership Initiative to Reduce Preventable Adverse Drug Events and its facilitation of multidisciplinary, multifaceted systems approaches for the enhancement of patient safety and prevention of health care errors.

The best practices put forth today by the National Patient Safety Partnership include a "call to action" for ongoing collaboration and research to identify better practices. To this end, the NPSF is convening a pharmaceutical safety workshop on June 10-11, 1999 in Washington, DC. Representatives from all dimensions of the pharmaceutical safety chain – ranging from pharmaceutical research and design, regulation, prescribing, administering, dispensing, monitoring, and consumer end use – will convene to identify their roles and responsibilities for the safe and appropriate use of pharmaceuticals. Expected outcomes of this workshop include a consensus on the strengths and vulnerabilities of the system and the identification of existing tools and resources, and those that are still needed, to responsibly address pharmaceutical safety issues.

Founded in 1997, the National Patient Safety Foundation is a nonprofit research and education organization dedicated to the measurable improvement of patient safety in the delivery of health care. The Foundation has formed a unique partnership of health care clinicians, institutional providers, health product manufacturers, researchers, legal advisors, consumer advocates, regulators, and policy makers among its board of directors. Working collaboratively with its broad base of constituents, the NPSF is leading the patient safety movement by raising awareness, building a knowledge base, creating a forum for sharing that knowledge, and facilitating the implementation of practices that improve patient safety.

For further information about the activities of the NPSF, visit its web site at www.npsf.org.

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NATIONAL PATIENT SAFETY PARTNERSHIP

MEDIA STATEMENT
May 12, 1999

OVERHAUL OF HEALTH CARE PROCESSES NEEDED TO INCREASE PATIENT SAFETY

The Institute for Healthcare Improvement (IHI) is a non-profit organization committed to developing systems of care that ensure patients receive safe and timely care that results in the best possible health outcome.

IHI has been working on patient safety issues for many years and, as a member of the National Patient Safety Partnership, believes that reducing adverse drug events is a critical and achievable step in ensuring a safe health care system. The problem is well understood, the solutions well documented, and now is the time to commit to solving this grave problem together.

According to IHI CEO and President, Donald M. Berwick, MD, "Error rates in medicine are much too high for the safety and well-being of patients. Yet the traditional approach of blaming individuals for mistakes doesn't get at the heart of the real problem. What's needed -- and what actually reduces and prevents errors -- is a redesign of work systems," Dr. Berwick says. The system for processing a medication order is complex, involving multiple individuals, groups and departments. "In addition, time pressures, excessive work loads, variations in practices and the structure of the patient care environment contribute to inefficiencies and provide opportunities for error," says Dr. Berwick. "Health care organizations have a moral obligation to create systems of care that are 100% error-proofed."

Reducing Adverse Drug Events

According to research studies published in the January 1997 issue of *The Journal of the American Medical Associa*tion, each year between 770,000 and 2 million hospital patients experience what is known as an adverse drug event, such as respiratory arrest, kidney failure, rashes and itching, diarrhea and vomiting, costing $4.2 billion. Furthermore, studies show that nearly one-third of all adverse drug events are preventable.

In 1996 and 1998, IHI sponsored Collaboratives on Reducing Adverse Drug Events and Medical Errors involving nearly 100 organizations across the US. Under the guidance of improvement and medical experts, these organizations prevented and reduced medication errors -- some by as much as 50 percent -- by redesigning work processes and systems. These six-month-long Collaboratives teach safety principles and methods commonly used by other industries (e.g., aviation) and focus efforts on six key areas: improving prescribing practices; safe handling of lethal drugs; standardizing the medication process; improving access to information; improving chemotherapy safety; and facilitating error reporting.

In addition, technologies that vastly improve the safety of medication systems are available, including computerized physician order entry systems, bar-coded dispensing and administration systems, and automated dispensing systems on nursing units tied to pharmacy computers. Yet these technologies are slow to be adopted due to the expense and lack of understanding about errors and error prevention on the part of many health care executives.

About IHI

Founded in 1991 and based in Boston, IHI is an independent, non-profit organization working to improve health care quality worldwide by fostering collaboration, rather than competition, among health care organizations. Specific goals IHI works toward include: improved public health; better clinical outcomes; reduced costs that do not compromise quality; greater access to care; an easier to use health care system; and improved satisfaction among individuals and communities. Visit our web site at www.ihi.org for more information.

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HEALTH AFFAIRS

The Department of Defense strongly supports the efforts of the National Patient Safety Partnership to improve healthcare and patient safety through the prevention of adverse drug events.

The 16 best practices identified by the Partnership are important steps to be taken by healthcare organizations, purchasers, physicians, nurses, pharmacists and patients. These steps are based on strong research and clinical experience. They include improved medication packaging, labeling and dispensing, dosage adjustments for children and the elderly, and active involvement of patients. Providers, healthcare organizations and manufacturers should support these measures under the basic premise of medicine – first, do no harm.

In the Military Health System, many of the best practices endorsed by the National Patient Safety Partnership are widely used. Our military pharmacists work with patients to inform them of the need to review their medications, including over the counter medications, with their healthcare providers. Many of our pharmacies have patient education offices specifically designed to offer counseling regarding medications and to respond to patient questions about their prescriptions. Many also have programs where the pharmacists make daily rounds with the healthcare team for all inpatients, which offers the opportunity to discuss pharmaceutical needs of each patient and identify potential problems.

Our automated Composite Healthcare System (CHCS) identifies patients' allergies and drug regimens in each computer record. This system also allows us to make extensive use of computer drug order entry and barcoding. An important new initiative is the new Pharmacy Data Transaction System (PDTS) that will link our military medical facilities, our Mail Order Pharmacy and the commercial pharmacies our patients use to give us an accurate record of all their prescription medications. This new information system will be an important tool in preventing adverse drug events.

Military medical facilities take special precautions for the storage and use of high hazard drugs such as chemotherapy agents. They also use unit dose systems and pharmacy-based IV preparation to minimize the risk of error.

Within the Military Health System, our pharmacists are vital members of the Healthcare Team. That team collaborates daily on how to improve healthcare and ensure the safety of our patients. This collaboration takes place in the policy-making setting as well as in our hospitals and clinics. We strongly support the Partnership's efforts to reach out to the spectrum of players involved in the care of our patients: providers, healthcare organizations, pharmaceutical industry, and patients themselves.

The Department of Defense continues to seek opportunities to improve the care of our beneficiaries and strongly endorse the best practices identified by the National Safety Partnership as important steps to make medications safer for all our patients.

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Statement of

Beverly L. Malone, PhD, RN, FAAN
President
American Nurses Association

on the launch of the
National Patient Safety Partnership's

Preventable Adverse Drug Events Initiative

May 12, 1999

Today is Florence Nightingale's birthday, the culmination of National Nurses Week. Nightingale is considered the founder of modern nursing. What better day for the American Nurses Association to join with the National Patient Safety Partnership to launch NPSP's Preventable Adverse Drug Events Initiative?

Adverse drug events are a serious public health care problem because of the large number of drugs, doses, and drug treatment regimens currently available and the many changes in the manner in which health care is being provided today. The members of NPSP believe there are significant patient safety improvements that can be made through the prevention of adverse events associated with the prescribing, dispensing and administering of medications. To that end, it advances this initiative aimed at reducing preventable adverse drug events.

America's health care consumers need more concrete and readily available information about what to do in partnership with their nurse or physician to ensure better medication information exchange. The word must get out to as many as possible.

The registered nurses of America, through representation by the American Nurses Association in the National Patient Safety Partnership, share a keen interest in advancing quality, safe practices for those receiving health care. Nurses have first-hand awareness that adverse events related to drug prescription, practices, packaging procedures and systems occur all too often. ANA supports the NPSP's call for improving outcomes by prevention. The identification of best practices or model practices is certainly the way to begin that process.

Nurses are reassured to see the NPSP's "questions patients should always ask about medications" and are encouraged by the outline of current best practices for patients/consumers, providing organizations and practitioners, and purchasers. As the only full-service professional association for the country's 2.6 million nurses, ANA believes quality safe patient outcomes begin with individual responsibility.

The ANA and the NPSP call on health care consumers, patient advocacy groups, the pharmaceutical industry, health care practitioners and health care organizations to make a commitment to adopt certain practices and to work together to implement them, as well as to develop additional ways to reduce adverse drug events.

Here are just two examples of such practices:

--We urge the prominent display of critical patient information, such as drug allergies and medication regimens, on every patient record. Dosage adjustments for children must be highlighted. We must not continue to consider children as little adults and apportion care delivery as such. We must take a similar approach with the frail elderly.

--We must limit accessibility to, and control the use of, highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.

Taking just these two steps would cost little or nothing to implement. However, ANA and the NPSP recognize that an investment may be required for some, and we call upon health care organizations and the pharmaceutical industry to make the investment in the interest of patient safety.

ANA stands strongly behind the position that the health care and pharmaceutical industries must launch and sustain collaborations directed toward systematic approaches to the prevention of prescription drug errors. Nurses challenge these industries to conduct the needed research as well as to seek collaborations to identify better practices in the future. Defining practices that can predictably effect improvement in terms of increased safety and cost-effectiveness is part of all our jobs.

Integral to such an activity is a non-punitive culture that enhances and supports reporting of adverse or unexpected events to relevant oversight bodies, and that provides feedback about resulting lessons learned and system changes aimed at preventing such events in the future. Our systems and processes are often flawed, and, in the haste to get a quick fix, blame is placed on individuals when an extended look for the source of difficulty is needed.

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Note to Media: To interview registered nurses who can speak on preventable adverse drug events, contact Michael Stewart in the American Nurses Association's Communications Department at (202) 651-7048, or e-mail:RN=RealNews@ana.org. Visit ANA's webpage on patient safety issues at http://www.nursingworld.org/rnnoharm.

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The American Nurses Association is the only full-service professional organization representing the nation's 2.6 million Registered Nurses through its 53 constituent associations. ANA advances the nursing profession by fostering high standards of nursing practice, promoting the economic and general welfare of nurses in the workplace, projecting a positive and realistic view of nursing, and by lobbying the Congress and regulatory agencies on health care issues affecting nurses and the public.

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The National Patient Safety Partnership is a public-private partnership dedicated to improving health care in general and patient safety in particular by reducing adverse events and untoward outcomes of health care or health care-related processes.

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SENTINEL EVENT **ALERT**

Joint Commission
on Accreditation of Healthcare Organizations

A publication of the Joint Commission on Accreditation of Healthcare Organizations

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"The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple -- organizations must take it off the floor stock of all units. It is one of the best examples I know of a 'forcing function' -- a procedure that makes a certain type of error impossible."
Lucian L. Leape, M.D.
Harvard School of Public Health

New Publication

We are pleased to introduce the first issue of *Sentinel Event Alert,* a periodic publication dedicated to providing important information relating to the occurrence and management of sentinel events in Joint Commission-accredited health care organizations. *Sentinel Event Alert,* to be published when appropriate as suggested by trend data, will provide ongoing communication regarding the Joint Commission's Sentinel Event Policy and Procedures, and most importantly, information about sentinel event prevention. It is our expectation and belief that in sharing information regarding the occurrence of sentinel events, we can ultimately reduce the frequency of medical errors and other adverse events.

Initially, *Sentinel Event Alert* will be mailed to the organization chief executive officers and Joint Commission survey coordinators, however, it is expected that eventually *Sentinel Event Alert* will be sent via broadcast fax. In the future, staff from the Joint Commission will be contacting your organization to collect appropriate fax and E-mail addresses.

While the topic of this first issue is particularly relevant to acute care facilities, we will share information of relevance to all accredited organizations in future issues.

"Unfortunately, there are too many in health care who feel that if it hasn't happened to them, the adverse experiences of others do not apply. That is why potassium chloride concentrate vials can still be found in patient care areas."
Michael Cohen, MS, FASHP, President, Institute for Safe Medication Practices

Medication Error Prevention -- Potassium Chloride

In the two years since the Joint Commission enacted its Sentinel Event Policy, the Accreditation Committee of the Board of Commissioners has reviewed more than 200 sentinel events. The most common category of sentinel events was medication errors, and of those, the most frequently implicated drug was **potassium chloride (KCl).** The Joint Commission has reviewed 10 incidents of patient death resulting from misadministration of KCl, eight of which were the result of direct infusion of concentrated KCl. In all cases, a contributing factor identified was the availability of concentrated KCl on the nursing unit. In six of the eight cases, the KCl was mistaken for some other medication, primarily due to similarities in packaging and labeling. Most often, KCl was mistaken for sodium chloride, heparin or furosemide (Lasix).

***Issue For Consideration*: In light of this experience, the Joint Commission suggests that health care organizations NOT make concentrated KCl available outside of the pharmacy unless appropriate specific safeguards are in place.**

The Joint Commission makes this information available to assist health care organizations in reducing their risk of sentinel events. Health care organizations should consider the risk described in the Sentinel Event Alert, *and determine their own most appropriate and effective responses to that risk.*

DEPARTMENT OF VETERANS AFFAIRS
UNDER SECRETARY FOR HEALTH
WASHINGTON DC 20420

May 12, 1999

Over the past four years, the Veterans Health Administration (VHA) has undergone an unprecedented transformation, changing from a hospital-based, provider-focused collage of facilities to an outpatient-based, patient-focused system of care that is grounded in universal primary care. As part of its transformation, the VHA has markedly expanded and enhanced its quality management activities, and especially those dealing with patient safety.

As the largest integrated healthcare system in the U.S., and one that is publicly funded, the VHA believes it has a special obligation to continually seek ways to improve patient safety and to share what it learns and does with others in the industry. The VHA has put into place a number of patient safety policies and practices that it believes other healthcare organizations can and should consider. These include:

- removing concentrated potassium chloride from unit stock and restricting it to pharmacy-managed IV admixture programs;*
- limiting unit stock levels and accessibility to other high hazard medications (e.g, concentrated epinephrine, digoxin, pancuronium, verapamil);*
- instituting computerized patient record systems that incorporate provider and pharmacy alerts; and
- instituting barcoding to reduce medication and transfusion errors.*

In addition, VHA has established and funded ($6 million) four Patient Safety Centers of Inquiry.* These centers, in collaboration with their academic partners, will conduct research to apply existing knowledge, as well as producing new knowledge, about root causes of error and avoidable adverse events resulting from healthcare. The Centers were selected after a national competition and are sited in Palo Alto, California; Cincinnati, Ohio; White River Junction, Vermont; and Tampa, Florida. They will especially focus on applying what is known from other high-risk industries and on disseminating knowledge that can be put to immediate use.

VHA is also committed to developing public-private collaborations with other healthcare and healthcare support organizations. It is through such relationships that great strides in patient safety improvement can be made. VHA also draws on the experience and knowledge of organizations such as the Institute for Healthcare Improvement and the Joint Commission for Accreditation of Healthcare Organizations to move the patient safety agenda forward.

The VHA is committed to improving patient safety and will continue to seek new partners and leverage its position in the industry and the market to do so.

Under Secretary for Health, Kenneth W. Kizer, M.D., M.P.H.
For additional information, call 202.273.5700.

**Copies of relevant policy documents and other related items are attached.*

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 99-009

March 23, 1999

NEED FOR ENHANCED ACCOUNTABILITY OF SELECTED POINT-OF-CARE MEDICATIONS

1. PURPOSE: This directive establishes Veterans Health Administration (VHA) policy regarding the need for enhanced accountability of selected ward-stocked and other point-of-care medications.

2. BACKGROUND

a. All medications have the potential to do harm to patients.

b. In the prescribing, dispensing, distribution, and administration of medications great efforts are put forth by all healthcare professionals to reduce the likelihood of any adverse occurrence due to the medication. Over the past 20 years many systems to reduce error in the medication use process have been developed. These systems include machine readable labeling, computerization, software development, automated dispensing equipment, and changes in drug packaging. To date, the medication use area with the least accountability and control is non-patient specific distribution to point-of-care locations.

c. This directive alerts field stations to the need for enhanced accountability and control of medications distributed directly to point-of-care locations. The nature of the use of certain pharmaceuticals requires distribution processes that assure immediate access in cases of emergency and/or continuous access in cases of chronic need or fluctuating patient response. Such medications may be pre-distributed to point-of-care locations as ward or clinic stock, emergency cart stock, for use off tour, etc., rather than distributed for an individually identified patient.

d. Characteristics of some of these pharmaceuticals present potential for significant adverse events, including intentional untoward use. Numerous medicinals are susceptible to causing significant harm or death if mistakenly or intentionally misused. Some of these agents are insulin, potassium, epinephrine, digoxin, lidocaine, pancuronium, succinyl choline, atropine, verapamil and diazepam.

e. Recently,VHA Directive 98-026, dated May 8, 1998, required that ward-stocked potassium chloride concentrate, USP, be removed from all patient care areas.

3. POLICY: It is VHA policy that all necessary actions shall be taken to reduce the likelihood of intentional or unintentional untoward use of selected point-of-care medications. To achieve this end, appropriate controls over ward-stocked medications shall be instituted at all VHA health care facilities to reduce the likelihood of untoward use of these medications.

THIS VHA DIRECTIVE WILL EXPIRE MARCH 23, 2004

4. ACTION

a. To maintain appropriate availability of these, and similarly stocked agents, provide for patient safety, and facilitate accountability of doses dispensed, facilities are advised to immediately review ward stock processes and resource utilization, and to take corrective actions as necessary to assure:

(1) Stock levels are limited to necessary quantities as determined by actual use.

(2) Stock locations are appropriate and necessary as determined by actual use.

(3) A process of accountable distribution is in place.

(4) Medications are stored in a secure manner.

(5) Access to medication is limited to those few persons who really need it.

(6) Administration is documented in the permanent patient and hospital/clinic record.

(7) Means to track return and destruction of outdated and unused products (e.g., a return goods contract) is in place.

(8) A means to reconcile distribution with use exists.

b. Local Pharmacy and Therapeutics Committees will review the issue and consider point-of-care automated dispensing systems to support the manual accountability systems currently in place.

c. Within 60 days of the date of issuance of this Directive, each Veterans Integrated Service Network (VISN) shall submit a report to VHA Headquarters, Pharmacy Benefits Management Strategic Healthcare Group (PBM SHG) (119) on each facility's specific policy and procedures for compliance with subparagraph 4a(1) through (8). Such policy and procedures shall, at a minimum address the following medications: (1) insulin, (2) potassium, (3) epinephrine, (4) digoxin, (5) lidocaine, (6) pancuronium, (7) succinyl choline, (8) atropine, (9) verapamil and (10) diazepam.

d. PBM SHG will compile this information to determine common procedures, as well as possibly identifying potential "model" practices and ineffective practices. ***NOTE:*** *Further guidance may be issued to the field subsequent to review of these procedures*.

e. The Office of the Medical Inspector will be responsible for spot checking compliance with the requirements of this Directive.

5. **REFERENCES:** VHA Manual M-2, Part VII.

6. FOLLOW UP RESPONSIBILITY: The Chief Consultant, Pharmacy Benefits Management Strategic Health Group (119), is responsible for the content of this Directive.

7. RESCISSIONS: This VHA Directive will expire March 23, 2004.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 98-026

May 8, 1998

VA POLICY REGARDING CONCENTRATED POTASSIUM CHLORIDE SOLUTIONS FOR INJECTION FOR USE IN MEDICAL TREATMENT FACILITIES

1. PURPOSE: This directive establishes Department of Veterans Affairs (VA) policy regarding the use of concentrated potassium chloride injection solutions.

2. BACKGROUND

a. In recent years, numerous reports have been published in the medical literature of adverse events and deaths caused by errors in the use of concentrated potassium chloride for injection. This matter has been discussed during numerous VA national pharmacy conference calls and many facilities have already removed concentrated potassium chloride and other hypertonic injectables from patient care areas. No specific national policy concerning the use of concentrated potassium chloride injection in VA medical facilities has been promulgated.

b. VA policy requires that a pharmacy managed Intravenous (IV) admixture program be responsible for the labeling, preparation, and distribution of IV admixtures. Understanding that some IV admixtures may not be prepared by the Pharmacy Service, practices and policies must be in place to assure the IV admixtures that are not prepared by the Pharmacy Service are compatible with the policies that govern the IV admixtures prepared by Pharmacy Service.

c. On January 20, 1998, the Under Secretary for Health issued a memorandum to all VA medical facilities on the subject of concentrated potassium chloride injection.

3. POLICY

a. Concentrated potassium chloride solutions for injection will not be stored on any wards, intensive care units, surgical suites and similar sites as ward stock.

b. Concentrated potassium chloride solutions will only be utilized as part of a pharmacy-managed IV admixture program. Therefore, storage of the medication will be in the pharmacy and will be the responsibility of the Pharmacy Service.

c. To meet patient needs, the use of manufactured "pre-mixed" large volume solutions, including those with potassium chloride, may be used in conjunction with a pharmacy-managed IV admixture program.

THIS VHA DIRECTIVE WILL EXPIRE MAY 8, 2003

4. ACTION

a. All VA medical facilities will ensure that any concentrated potassium chloride solution is removed from all wards, intensive care units, operating suites, and clinics.

b. All VA medical facilities will establish medication use policies that include guidance regarding safe administration of potassium chloride solutions for injection. Additionally, these policies shall specifically state that it is VA policy not to have concentrated potassium chloride and other hypertonic injectable solutions on the wards and similar sites, that normal or routine VA practice is for IV solutions to be mixed centrally, and that unit dose drug distribution is required for inpatient areas.

5. REFERENCES: None.

6. FOLLOW-UP RESPONSIBILITY: The Chief Consultant for Pharmacy Benefits Management Strategic Healthcare Group (119) is responsible for the contents of this directive.

7. RESCISSIONS: This VHA Directive expires May 8, 2003.

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health

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NATIONAL PATIENT SAFETY PARTNERSHIP

Charter

Purpose

The National Patient Safety Partnership (NPSP) is chartered as a voluntary public-private partnership to improve patient safety by reducing preventable adverse events and untoward outcomes of healthcare or healthcare related processes. Such unintended consequences of healthcare result in unnecessary patient morbidity and mortality, and they occur in all healthcare delivery systems and with all financing mechanisms. Unless the underlying reasons for such occurrences are determined and shared throughout the healthcare sector, each hospital or healthcare system must itself experience the adverse event before it can re-engineer for safety. Barriers to the broad sharing of lessons learned as a result of adverse events must be addressed. Development of a national strategy to address this problem can occur when government and the private sector join together with patient and consumer advocacy groups to address the problem and the culture in which it exists. This partnership will promote that process.

Goal and Objectives

The primary goal of the NPSP is to align the essential elements - people, including patients; processes; and structures - into a strategic framework that can be applied to reduce untoward consequences of healthcare. To this end it will:

1. Review existing patient safety research and identify needs for additional investigation;
2. Identify and learn from the experience of relevant safety interventions from non-healthcare industries (e.g., aviation, highway traffic, and nuclear power);
3. Review existing patient safety databases and identify needs for a national monitoring system and barriers to creating such a system;
4. Promote individual healthcare organization commitment to patient safety improvement;
5. Promote system-wide protocols for improving patient safety;
6. Promote system-wide structure/mechanisms for timely exchange and feedback of patient safety related information;
7. Identify performance measures and benchmarks for patient safety;
8. Involve healthcare consumers, including patients, as active participants in improving patient safety and explore with them the role of consumer in promoting patient safety;
9. Develop consensus on a national agenda to enhance patient safety;
10. Advance a national position (policy) regarding patient safety and take action to facilitate its local implementation; and
11. Promote awareness and sensitivity to these issues in the education and training of health care professionals.

Organization

The NPSP is formed as a non-binding public-private partnership of the following charter organizations.
Department of Veterans Affairs;
American Hospital Association;
American Medical Association;
National Patient Safety Foundation at the AMA;
American Nurses Association;
Association of American Medical Colleges;
Joint Commission on Accreditation of Healthcare Organizations; and,
Institute for Healthcare Improvement.

To carry out its activities, the NPSP will work collaboratively with its member organizations and others to address patient safety with an eye toward accelerating progress toward nationwide improvement in American healthcare systems. It will neither promote nor endorse particular products nor services to improve patient safety of its members or others.

The NPSP will organize itself to achieve the goals it has established.

Process

To achieve the goals and objectives of this collaboration, the NPSP will conduct meetings with a frequency, and by convenient methods, to meet its goals. It will make decisions about its management, take actions, make membership decisions, determine when and how it will meet, determine how joint initiatives and correspondence will be managed, submit reports and establish positions as needed to support the partnership.

It will sponsor educational activities that bring together the member organizations and other organizations with similar purposes to develop consensus on a national patient safety agenda.

Support

Primary support for the effort of the NPSP is the collaboration of its member organizations. The Veterans Health Administration, Department of Veterans Affairs, will serve as lead agency to coordinate the efforts.